

**REMARKS**

The applicants thank the Examiner for the thorough examination of the application. The specification has been amended to insert subject headings and to improve the format. The paragraph starting at page 4, line 19 of the specification has been amended to correct minor errors and to better correspond with the original German text. No new matter is believed to be added to the application by this Amendment.

**Status Of The Claims**

Claims 1-24 are pending in the application. Support for the amendments to claim 1 can be found in the specification at page 4, 1<sup>st</sup> paragraph; page 5, 4<sup>th</sup> paragraph; page 5, last paragraph; page 10, last paragraph and in Figure 2. The claims have been amended to recite a “carrier layer (1)” and a “matrix layer (2)” that finds support at, e.g., page 4, 3<sup>rd</sup> paragraph of the specification. The claims have been amended to improve their language. Claims 17-19 have been amended not to be “use” claims. Claim 23 is amended to recite only one of two possible alternatives and therefore to clarify the text. New claim 24 recites language deleted from claim 23.

**Rejection Of Claims 17-19 Under 35 U.S.C. §§101 and 112**

Claims 17-19 are rejected under 35 U.S.C. §101 as being non-statutory “use” claims. Claims 17-19 are rejected under 35 U.S.C. §112, second

paragraph as being indefinite for failing to set forth a proper process claim. Applicants traverse.

Claims 17-19 have been amended not to be “use” claims but to be process claims having at least one positive process step. Claims 17-19, as amended, thus are statutory process claims that are clear, definite and have full antecedent basis.

These rejections are overcome and withdrawal thereof is respectfully requested.

**Rejections Under 35 U.S.C. §§102(b) And 103(a) Over Griffin**

Claims 1-3, 5-7, 10-12, 14-16 and 20-23 are rejected under 35 U.S.C. §102(b) as being anticipated by Griffin (EP 0 010 987). Claims 4, 8, 9, 13 and 17-19 are rejected under 35 U.S.C. §103(a) as being obvious over the single reference of Griffin. Applicants traverse.

**The Present Invention And Its Advantages**

The present invention pertains to preparations containing active and/or auxiliary substances, for the time- and/or dose-controllable release of these substances. These preparations contain at least two layers (a carrier layer and a matrix layer) in rolled or folded form. In one preferred embodiment of the invention, the concentration of the active substance(s) may be different in relation to the longitudinal extension of the active substance containing layer.

The present invention has many embodiments, and a typical embodiment can be found in claim 1:

1. A preparation containing active and/or auxiliary substance(s), for the time- and/or dose-controllable release of said substances, comprising a laminate made up of at least a carrier layer (1) and a matrix layer (2), said laminate being in rolled or folded shape, wherein
  - a) the matrix layer (2) has a longitudinal extension, contains at least one active or auxiliary substance, and is continuous at least in sections thereof,
  - b) at least one of the parameters of width and concentration of the active and/or auxiliary substance of this layer is not constant in relation to said longitudinal extension, and
  - c) said carrier layer (1) is continuous and possesses a lower moisture permeability than the matrix layer (2).

*Distinctions Of The Invention Over Griffin*

Griffin pertains to a sustained drug release device for a ruminant animal. Figure 1 of Griffin shows an erodable sheet 1 heat welded to a sheet 2 of insoluble ethylene vinyl acetate copolymer. Figure 3 of Griffin shows this construction loosely rolled up using strips of paper 3.

Griffin fails to disclose or suggest a laminate having an active substance containing matrix layer that has at least one of the parameters of width and concentration of the active and/or auxiliary substance not being constant in relation to the longitudinal extension of the layer, as is set forth in claim 1 of the present invention.

At page 3 of the Office Action, the Examiner turns to page 5, lines 1-14 of Griffin and asserts: "The particular release profiles can be determined through

routine experimentation and change to fit the needs of the patient.” However, this passage merely relates to the possibility of altering the overall erosion characteristics of the erodible sheet by incorporating a biodegradable material to improve the erodability of the erodable sheet. This passage does not disclose any “particular profile,” nor does it disclose a laminate having an active substance-containing layer having a variable concentration of active substances along its length, or having a variable width in the longitudinal direction of the layer.

That is, the active substance containing sheets described by Griffin (and shown in Figures 1 and 3 of Griffin) have a width that is constant in the longitudinal direction, and the concentration is also uniform within the area of the sheets (see Griffin at page 9, lines 3-6 and page 10, lines 4-5 and 29-30). In comparison, Figures 2-4 of the present invention show non-uniform geometric profiles.

Also, the Examiner relies upon “routine experimentation” in alleging anticipation under 35 U.S.C. §102(b) (page 3, paragraph 5 of the Office Action). However, “routine experimentation” is a criteria for obviousness under 35 U.S.C. §103. *See MPEP* 2144.05.

Griffin thus clearly fails to anticipate the invention.

At page 4 of the Office Action, the Examiner admits that Griffin fails to disclose the inclusion of active agents in the water-insoluble layer. The Examiner then asserts that the limitation lacks criticality and could further be obtained using routine experimentation.

However, the Examiner is using the single reference of Griffin to allege obviousness. To establish a *prima facie* case of obviousness, “the prior art reference (or references when combined) must teach or suggest all the claim limitations.” *MPEP* §2143. In addition, if a reference needs to be modified to achieve the claimed invention “there must be a showing of a suggestion or motivation to modify the teachings of that reference to the claimed invention in order to support the obviousness conclusion.” *Sibia Neurosciences Inc. v. Cadus Pharmaceutical Corp.*, 225 F.3d 1349, 55 USPQ2d 1927 (Fed. Cir. 2000).

In this case, the Examiner fails to point out a teaching or suggestion in Griffin itself pertaining to obtaining a non-uniform concentration of active and/or auxiliary substance in relation to the longitudinal extension of the layer. The Examiner merely maintains that the invention would be obvious to one of ordinary skill.

However, Griffin utterly fails to offer the slightest hint that might indicate that various release profiles could be obtained by using a matrix layer in which at least one of the parameters of width and concentration of the active and/or auxiliary substance is not constant in relation to the longitudinal extension of the layer.

Griffin thus fails to anticipate claim 1. Griffin would also fail to motivate a person having ordinary skill in the art to produce the invention of claim 1. A *prima facie* case of obviousness has thus not been made. Claims depending upon claim 1 are patentable for at least the above reasons.

These rejections are overcome and withdrawal thereof is respectfully requested.

**Information Disclosure Statement**

The Examiner is thanked for considering the Information Disclosure Statement filed May 22, 2002 and for making the initialed PTO-1449 form of record in the application in the Office Action mailed December 16, 2004.

**Foreign Priority**

The Examiner has acknowledged foreign priority.

**The Drawings**

The Examiner is respectfully requested to indicate whether the drawing figures are acceptable in the next official action.

**Conclusion**

The Examiner's rejections have been overcome, obviated or rendered moot. No issues remain. The Examiner is accordingly respectfully requested to allow the application.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Robert E. Goozner, Ph.D. (Reg. No. 42,593) at the telephone number of the undersigned

Application No.: 10/089,444

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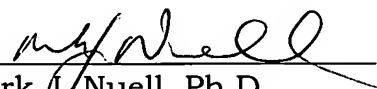
below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), Applicant(s) respectfully petition(s) for a three (3) month extension of time for filing a reply in connection with the present application, and the required fee of \$1020.00 is attached hereto.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Respectfully submitted,

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By   
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